

Applicants: Thompson et al.  
Serial No. 09/825,909  
Page 6 of 10

### **REMARKS**

In accordance with the forgoing, claims 1, 14, 19, and 20 are canceled, claims 2-5, 15-18, 21 and 24 are amended and new claim 25 has been added (comprising prior claim 19 with added limitations regarding the sensor); thus, claims 1-5 and 15-18, and 21-25 are currently pending and under consideration for substantive examination. The following remarks are respectfully submitted.

Applicants request entry and favorable consideration of the amendments and remarks presented herein.

### **Claim Rejection Under 35 U.S.C. § 112**

In the Office Action, "[c]laims 1-5 and 20-25" [sic - there was no claim 25] were rejected by the Examiner under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement and the amendment filed 28 January 2004 is objected to for similar reasons (but under 35 U.S.C. §132).

However, Applicants assert that the specification in fact supports the subject matter claimed in the amended claims submitted for examination on 28 January 2004.

For example, the '654 patent to Wohltmann et al. is incorporated into the specification (see pg. 5, ll. 1-5) and describes a vibratory mode of operation (albeit the term used is "perturbations"):

As disclosed in U.S. Patent No. 5,904,654 to Wohltmann et al, incorporated herein by reference in its entirety, unit 18 includes an exciter and a detector mounted on a common support for inducing perturbations into the body and detecting the perturbations after they travel a distance through the body in order to detect a hemoparameter.

Further support for the claimed subject matter is from the '654 patent, which recites the following reference on the face sheet of the '654 patent:

Applicants: Thompson et al.  
Serial No. 09/826,909  
Page 7 of 10

**"H. Shimazu et al., Vibration technique for indirect measurement of diastolic arterial pressure in human fingers, Medical & Biological Engineering & Computing (1989), vol. 27, 130-136." (emphasis added.)**

As a single example of the fact that vibratory transducer(s) are central to the '654 patent can be found in claim 14 of the '654 patent:

**14. An exciter-detector unit for measuring physiological parameters at selected positions on the body of a patient comprising: an exciter for transmitting vibrations into the patient at a first location at said position, and a detector spaced from said exciter for detecting a hemoparameter at a second location to provide an output signal containing a component of a physiological parameter waveform and a component of received vibrations, and an elongated support member for supporting said exciter and detector at a predetermined fixed spacing along said elongated support member. (emphasis added.)**

Furthermore, at col. 4, ll. 41-52 the '654 patent provides the following support for the notion that vibration is one of several sensing techniques described and supported by the specification as originally filed:

The detector can use a diverse selection of technologies, each of which may pertain to a separate embodiment, and each of which has the common feature of being able to detect a vibration which has propagated through a portion of the body. Examples of appropriate technologies include, but are not limited to piezoelectric, photo-plethysmography, impedance plethysmography, other plethysmography, capacitive displacement, inductive displacement, doppler ultrasound/light, ultrasound and other wall displacement, microwave impedance, strain gage, tonometry and electronic flow meter. The following are descriptions of specific detector technologies.

Also, the '025 patent to Tavori - which forms the new basis of rejection herein - is also referenced and incorporated by reference into the specification as filed (at pg. 6, ll. 25-28):

Applicants: Thompson et al.  
Serial No. 09/825,909  
Page 8 of 10

Referring now to Figure 4, patch sensor or sensor 22 is shown in contact with the body of patient 10, as disclosed in U.S. Patent No. 5,724,025 to Tavori, incorporated herein by reference in its entirety.

The Tavori reference includes FIG. 7 which depicts sensors coupled to all peripheral limbs of a patient (copy appended hereto). Tavori also includes support for the "continuously collected physiological data," to wit:

The device is capable of being mounted comfortably on the person or animal being monitored, has small dimensions and body hugging capability. The device can be mounted on a limb, on the torso, neck or belly, or on the back or any place on the monitored body. The device can be moved all over the body to accommodate various medical diagnostics procedures. Furthermore, measurements are taken continuously or intermittently as preset by the operating software. The data are either continuously or intermittently transmitted to a stationary data retrieving system or stored for further or later processing. (emphasis added.)

Although Applicants suggest that the written description fully supports the claimed subject matter, Applicants reserve the right to augment the written description with subject matter incorporated by reference therein (e.g., text and drawings). If the Examiner would prefer such action, Applicants again suggest that the finality of the present action be withdrawn so that Applicants can receive the comprehensive examination of the claimed subject matter.

In addition to the foregoing, Applicants drafted the instant specification for an audience of skilled practitioners in the art and have the right to also benefit from principles of inherency that surely support the notion of multiple sensor locations, transducing modalities and the like as claimed herein.

#### **Claim Rejections Under 35 U.S.C. § 103**

In the Office Action, the Examiner rejected claims 1-2, 4-5, 14, 15 and 17-24 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 5,540,727 to Tockman et al. ("Tockman") in view of U.S. Pat. No. 5,724,025 to Tavori ("Tavori").

Applicants: Thompson et al.  
Serial No. 09/825,909  
Page 9 of 10

In the Office Action, the Examiner also rejected claims 3 and 16 as being unpatentable over Tockman in view of Tavori and further in view of U.S. Pat. No. 6,470,199 to Kopotic et al. ("Kopotic").

In connection with combining references to support an assertion of obviousness, it is well established that the Examiner bears the burden of establishing a *prima facie* case of obviousness. In re Oetiker, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). In doing so, the Examiner must determine whether the prior art provides a "teaching or suggestion to one of ordinary skill in the art to make the changes that would produce" the claimed invention. In re Chu, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995). A *prima facie* case of obviousness is established only when this burden is met.

With respect to the rejection of claims 1-2, 4-5, 14, 15 and 17-24 over Tockman in view of Tavori, Applicants respectfully suggest that inadequate support exists for the proposed combination. In addition, the combination fails to render the presently claimed invention, as amended, obvious.

With respect to the rejection of claims 3 and 16 over Tockman in view of Tavori in further view of Kopotic, Applicants herewith submit a declaration pursuant to 27 CFR 1.131 asserting prior invention of the what the inventors referred to as the "sock sensor" and claims 3 and 16 have been amended to incorporate the limitations of the respective independent claims from which they formerly depended, and thus focus on the sock sensor as described in the written description of the application (at page 8, ll. 15-21); namely:

Such a sensor could be used to measure a number of valuable physiological parameters including weight, ankle swelling for edema, and patient activity. Similar to sensors 18, ring sensor 20, and patch sensor 22, sock sensor 24 is adapted to be in data communications with IMD 12. Accordingly, sensor 24 would transmit data relating to vital signs of patient 10 to IMD 12 to thereby initiate control, modify the delivery of therapy or record the data for later follow-up retrieval and diagnostic review.

Applicants: Thompson et al.  
Serial No. 09/825,909  
Page 10 of 10

The invention of the sock sensor, as described and claimed herein occurred at least as early as September or October 1999. Thus, this ground of rejection stands traversed and should be withdrawn.

### CONCLUSION

There being no further outstanding objections or rejections, it is submitted that pending claims 2-5, 15-18, and 20-25 of the application are in condition for allowance. An early action to that effect is courteously solicited.

No amendment made was related to the statutory requirements of patentability unless expressly stated herein; and no amendment made was for the purpose of narrowing the scope of any claim, unless Applicant has argued herein that such amendment was made to distinguish over a particular reference or combination of references.

Finally, if there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned attorney to attend to these matters.

Respectfully submitted,

Date:

*8 July 04*

*Paul H. McDowall*

Paul H. McDowall  
Reg. 34,873  
Telephone: (763) 514-3351  
Customer No. 27581